Remarks

Claims 46, 72 and 73 are pending in this application. By this amendment, claims 46, 72 and 73 have been amended. Support for these amendments can be found throughout the specification and in particular, page 35, lines 31-39 and page 58, line 32 through page 59, line 3.

No new matter is added by this amendment. Consideration and allowance of the pending claims are requested.

Interview with Examiner Boesen

Applicants thank Examiner Boesen for discussing the pending Office action with their undersigned representative on July 13, 2010 and September 2, 2010. During these interviews, claim 46 was discussed. In particular, the amendment of claim 46 to remove the terms "host protein," "target sequence" and "HIV infection" were discussed. Also, during our September 2, 2010 interview, the pending enablement and written description rejections were discussed in light of the teachings of Murray *et al.* (*J. Virol.* 79(18): 11742-11751, 2005) and Chen *et al.* (*J. Biol. Chem.* 279(38): 40204-40208, 2004) provided herewith as Exhibits A and B, respectively. It is believed that this response is prepared in accordance with the suggestions made by Examiner Boesen.

Rejections under 35 U.S.C. §112, second paragraph

Claims 46, 72 and 73 are rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for reciting "wherein the host protein is encoded by a human Rab9 target sequence." Claim 46 has been amended to recite "a human Rab9 protein." Exemplary human Rab9 sequences are described in the specification, such as on page 35, lines 31-39. Applicants believe this amendment renders the pending 35 U.S.C. §112, second paragraph rejection moot and requests that it be withdrawn.

Rejections under 35 U.S.C. §112, first paragraph

Claims 46, 72 and 73 have been rejected under 35 U.S.C. §112, first paragraph as allegedly not being enabled by the specification for any HIV protein, any host protein and any Rab9 target sequence. In particular, the Office asserts that one of skill in the art would need to

conduct undue experimentation in order to determine which host proteins bind HIV proteins at all, before determining which agents decrease the binding of the HIV to the host protein. Applicants respectfully disagree with this rejection. However, in efforts to solely further prosecution, all claims have been amended to be directed to a method of identifying a compound that decreases binding of an HIV envelope protein to a human Rab9 protein. Therefore, the amended claims are directed to a specific type of HIV protein (*i.e.*, an HIV envelope protein) and a specific host/target sequence (*i.e.*, a human Rab9 protein) rendering this previous argument moot.

The Office further alleges that claims 46, 72 and 73 are not enabled because the specification does not include experimental data showing identification of a compound that decreases binding of an HIV protein to a host protein according to the claim method. Applicants respectfully disagree with this rejection. As noted by the Office, the specification includes working examples that discuss and contemplate various general methods that could be used to practice the claimed invention including the following: (1) assays for measuring inhibition of viral infection and assays screening for agents that decrease viral infection (Examples 10-13); methods of disrupting gene expression (Example 6); and methods to decrease viral infection by use of siRNA molecules (Example 3). Moreover, it has been now shown in the field that silencing Rab9 inhibits HIV replication (for Example see Figure 2 of Murray *et al., J. Virol.* 79(18): 11742-11751, 2005, Exhibit A) and that identifying a compound that targets Rab9 can be used to identify antiviral agents, including those agents to inhibit HIV (Chen *et al.*, *J. Biol. Chem.* 279(38): 40204-40208, 2004 (in particular, page 40204, column 2, lines 8-19 and Abstract), Exhibit B). Therefore, these studies support the claim that inhibiting Rab9 binding to an HIV protein can be used to identify molecules that inhibit such interaction. Finally, Applicants assert that the pending claims are to a screening method and performing such a screening method is routine to those of ordinary skill in the art. As such, Applicants believe that the claims as amended are enabled.

Claims 46, 72 and 73 are further rejected under 35 U.S.C. §112, first paragraph, as allegedly not providing sufficient evidence that Applicants were in possession of a representative number of species of the host proteins encoded by a human Rab9 target sequence that can be

useful in the claimed method of identifying a compound that decreased HIV infection. Applicants respectfully disagree with this rejection for at least the following reasons.

As discussed above, amended claims 46, 72 and 73 no longer recite "a human Rab9 target sequence." Instead, to further prosecution, such claims have been amended to recite "a human Rab9 protein." Exemplary human Rab9 sequences are described in the specification such as on page 35, lines 31-39. Further, the claims are amended to recite a specific HIV protein (an HIV envelope protein) as disclosed in the specification such as on page 58, lines 32-33. Moreover, the screening method as presently claimed involves contacting a human Rab9 protein with an HIV envelope protein and test compound, measuring binding of the HIV envelope protein to the human Rab9 protein and identifying a test compound capable of modulating such binding by detecting a decrease in such binding. The present specification provides a detailed description of how to screen for agents that decrease viral infection (see, page 58, line 18 – page 59, line 8 and Examples 10-13). Therefore, the specification clearly demonstrates to one of ordinary skill in the art that the Applicants were in possession of the claimed invention as of the date of invention. In particular, the skilled artisan can envision the detailed structures of both a human Rab9A protein and an HIV envelope protein as well as how to perform the present screening method upon the review of the specification. As such, Applicants believe the claims as amended satisfy the written description requirement of 35 U.S.C. §112, first paragraph.

Applicants believe that the amended claims are enabled and adequately described in the specification to satisfy the enablement and written description requirements of 35 U.S.C. §112, first paragraph, and all other requirements of patentability. As no prior art rejections have been made, allowance of claims 46, 72 and 73 is respectfully requested.

Conclusion

Applicants respectfully submit that the claims filed herewith are in condition for allowance. If any issues remain, Examiner Boesen is requested to contact the undersigned attorney to arrange a telephonic interview prior to the preparation of a subsequent action.

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Respectfully submitted,

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